#### 4270. FAMILY PLANNING SERVICES

- A. Background.--Section 1905(a)(4)(C) of the Act requires States to provide family planning services and supplies (directly or under arrangements with others) to individuals of childbearing age (including minors who can be considered to be sexually active) who are eligible under the State plan and who desire such services and supplies. Section 1902(a)(10)(A) specifies that family planning services be made available to categorically needy Medicaid recipients while §1902(a)(10)(C) indicates that the services may be provided to medically needy Medicaid recipients at the State's option. Section 1903(a)(5) provides that FFP is available at the rate of 90 percent for the cost of family planning services.
- B. Scope of Services.--The term "family planning services" is not defined in the law or in regulations. However, the Senate Report accompanying the law stresses Congress' intent of placing emphasis on the provision of services to "aid those who voluntarily choose not to risk an initial pregnancy," as well as those families with children who desire to control family size. In keeping with Congressional intent, you may choose to include in your definition of Medicaid family planning services only those services which either prevent or delay pregnancy, or you may more broadly define the term to also include services for the treatment of infertility. However, the Medicaid definition must be consistent with overall State policy and regulation regarding the provision of family planning services. You are free to determine the specific services and supplies which will be covered as Medicaid family planning services so long as those services are sufficient in amount, duration and scope to reasonably achieve their purpose. You must also establish procedures for identifying individuals who are sexually active and eligible for family planning services.
- 1. <u>Services Available For FFP 90 Percent Rate.</u>—In general, FFP at the 90 percent matching rate is available for the costs of counseling services and patient education, examination and treatment by medical professionals in accordance with applicable State requirements, laboratory examinations and tests, medically approved methods, procedures, pharmaceutical supplies and devices to prevent conception, and infertility services, including sterilization reversals.

FFP at the 90 percent rate is available for the cost of a Medicaid sterilization if a properly completed sterilization consent form, in accordance with the requirements of 42 CFR 44l, Subpart F, is submitted to you prior to payment of the claim.

2. Services Not Available For FFP 90 Percent Rate.--FFP at the 90 percent rate is not available for the cost of a hysterectomy (see §4435) nor for costs related to other procedures performed for medical reasons, such as removal of an intrauterine device due to infection. Only items and procedures clearly provided or performed for family planning purposes may be matched at the 90 percent rate. Abortions may not be claimed as a family planning service. (See §4430.) Similarly, transportation to a family planning service is not eligible for the 90 percent match. Transportation must be claimed as either an administrative cost or a State plan service, in accordance with your approved Medicaid State plan.

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## 4280. ESTABLISHMENT AND USE OF MEDICAID UNIQUE PHYSICIAN IDENTIFIER

A. <u>Background</u>.--Under §1902(x) of the Act, as provided by §4752 of OBRA 1990, the Secretary is required to establish a system for implementation by July 1, 1991. The system must provide for a unique identifier for each physician who furnishes services for which payment may be made under a State plan approved under title XIX of the Act.

The Secretary has required that all mechanized claims processing and information retrieval systems approved for incentive funding under §1903(a)(3) and (r) of the Act contain as file requirements all the data elements required by Part 11 of this manual. (See §§11300 and 11375.) Almost all States have systems approved in accordance with these sections of the statute and the requirements of Part 11. Consequently each State with such an approved system has a unique numbering system for all providers including physicians. The State is required to identify each provider practicing within a group practice by using the individual provider's unique number when filing claims for services rendered by that provider.

B. Establishment of the Requirement.--Effective July 1, 1991, the Secretary establishes each State's unique statewide provider numbers, which are already part of its approved system, as the identifiers required by \$1902(x). Those States and jurisdictions which do not have a system approved under \$1903(a)(3) and (r) of the Act are also bound by this statutory requirement to establish a statewide unique physician identifier and to fulfill the other requirements of this section and must implement the requirement contained in Part 11.

As permitted by §1902(x), the Secretary exercises discretionary authority in establishing a system which is different from the system established under §9202(g) of COBRA of 1985. The Secretary encourages States to use for cross reference, the Unique Physician Identification Number (UPIN) established under §9202(g), which is described in the Medicare Carriers Manual, Part 4, Professional Relations, Transmittal 1, §1001.

For planning purposes, States are advised that HCFA intends to require that States obtain the Medicare UPIN on all physician billings submitted for Medicaid reimbursement. This Medicaid requirement will be effective subsequent to the Medicare program requiring the physician UPIN as a condition of payment. Additional information regarding the schedule for adoption of the Medicare UPIN for purposes of the Medicaid program will be provided through a subsequent State Medicaid Manual issuance.

#### 4281. RESTRICTION ON PAYMENTS FOR PHYSICIAN SERVICES

A. <u>Limits on Payment of Federal Financial Participation (FFP).</u>--Effective October 1, 1991, §1903(i)(12) provides that payment may not be made for any amount expended for physician's services furnished on or after October 1, 1991 unless the claim for service includes the State's unique physician identifier.

All States with systems approved under §1903(a)(3) and (r) must accept and use, but not exclusively, the common claim form, Health Insurance Claim Form, HCFA 1500, for noninstitutional providers (physicians, durable medical equipment suppliers, laboratories, chiropractors, and podiatrists). The unique physician identifier required under §4280 must appear in the lower right corner block containing physician name, address, phone number and ID # or PIN #, and similarly on any alternative claim form accepted by the State, as a condition of FFP payment.

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States and jurisdictions which do not have approved systems must also establish a system of unique physician identifiers. For FFP purposes, each physician claim for services must clearly indicate the appropriate unique physician identifier as required by §§4280 and 4281.

# 4282. MAINTENANCE OF LIST OF PHYSICIANS BY STATES

A. Monthly Listing of Participating Physicians.—Under §1902(a)(58) of the Act, States are required to maintain a monthly updated list containing each physician's unique identifier, as required by §4280. The list must include all physicians who are certified to participate under the State plan. This

requirement applies to Medical Assistance for calendar quarters beginning after September 30, 1991.

All States and jurisdictions are bound by this statute to maintain such lists monthly as a State plan requirement.

## 4283. CONDITIONS FOR FOREIGN MEDICAL GRADUATE CERTIFICATION

- A. Conditions for Assigning Physician Identifiers to Foreign Medical Graduates.--All States and jurisdictions are bound by §4752(d) of OBRA 1990 to not assign a physician identifier to a foreign medical graduate student, as defined under §1886(h)(5)(D) of the Act, unless the individual has:
- 1. Passed the Foreign Medical Graduate Examination in the Medical Sciences defined in \$1886(h)(5)(E) of the Act;
- 2. Previously received certification from, or has previously passed the examination of, the Educational Commission for Foreign Medical Graduates; or,
  - 3. Held a license from one or more States continuously since 1958.
- B. <u>Effective Date.</u>--This requirement applies to issuance of physician identifiers applicable to services furnished on or after January 1, 1992.

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#### 4301. HOME RESPIRATORY CARE FOR VENTILATOR-DEPENDENT INDIVIDUALS

- A. <u>General.</u>--Prior to enactment of the Omnibus Budget Reconciliation Act of 1986 (OBRA-86) on October 21, 1986, the Medicaid program had no direct provision for home respiratory therapy services. Effective October 21, 1986, §9408 of OBRA-86 amends §1902(e) of the Social Security Act and permits optional coverage of home respiratory therapy services for ventilator-dependent individuals meeting conditions defined in subsection C.
- B. <u>Definition.</u>—"Respiratory care for ventilator-dependent individuals" means services provided on a part-time basis, not otherwise available under the State Medicaid plan, that are furnished in the patient's home by a respiratory therapist or other health care professional who the State determines to be trained in respiratory therapy. A recipient's home does not include a hospital, NF, ICF/MR, or other institution as defined in 42 CFR 435.1009.
  - C. <u>Conditions.</u>—Individuals receiving home respiratory therapy under this provision must:
    - o Be medically dependent on a ventilator for life support at least 6 hours per day;
- o Have been so dependent for at least 30 consecutive days (or the maximum number of days authorized under the State Medicaid plan, whichever is less) as an inpatient in one or more hospitals, NFs, or ICFs/MR;
- o But for the availability of these respiratory care services at home, would require respiratory care as an inpatient in a hospital, NF, or ICF/MR, and would be eligible to have payment made for such inpatient care under the State Medicaid plan;
  - o Have adequate social support services to be cared for at home;
  - o Wish to be cared for at home; and
- o Receive services under the direction of a physician who is familiar with the technical and medical components of home ventilator support and who has medically determined that in-home care is safe and feasible for the individual.
- D. <u>Limits on Comparability of Services</u>.--You are not required to make home respiratory services of the same amount, duration, and scope available to anyone except those who meet the specific conditions for coverage in subsection C.

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# 4302. OPTIONAL TARGETED CASE MANAGEMENT SERVICES - BASIS, SCOPE AND PURPOSE

The Consolidated Omnibus Budget Reconciliation Act (P.L. 99-272, COBRA) added §§1915(g)(1) and (g)(2) to the Act. These sections add optional targeted case management services to the list of services that may be provided under Medicaid. Section 1895(c)(3) of the Tax Reform Act of 1986 (P.L. 99-514) added case management services to the list of services in §1905 of the Act. Section 4118(i) of OBRA 1987 (P.L. 100-203) added a section discussing the qualifications of case managers for individuals with developmental disabilities or chronic mental illness. Both the Tax Reform Act and OBRA 1987 amendments are effective as if included in COBRA and are considered effective on April 7, 1986.

- A. Background.--Case management is an activity which assists individuals eligible for Medicaid in gaining and coordinating access to necessary care and services appropriate to the needs of an individual. Prior to the enactment of P.L. 99-272, States could not provide case management as a distinct service under Medicaid without the use of waiver authority. However, aspects of case management have been an integral part of the Medicaid program since its inception. The law has always required interagency agreements under which Medicaid patients may be assisted in locating and receiving services they need when these services are provided by others. Prior to the enactment of P.L. 99-272, Federal financial participation (FFP) for case management activities may be claimed in any of four basic areas:
- 1. <u>Component of Another Service.</u>—Case management may be provided as an integral and inseparable part of another covered Medicaid service. An example of this type of case management is the preparation of treatment plans by home health agencies. Since plan preparation is required as a part of home health services, <u>separate</u> payment for the case management component cannot be made, but is included in the payment made for the service at the Federal Medical Assistance Percentage (FMAP) rate.
- 2. Administration.--Case management may be provided as a function necessary for the proper and efficient operation of the Medicaid State plan, as provided in §1903(a) of the Act. Activities such as utilization review, prior authorization and nursing home preadmission screening may be paid as an administrative expense. The payment rate is either the 50 percent matching rate or the 75 percent FFP rate for skilled professional medical personnel, when the criteria in 42 CFR 432.50 are met.
- 3. Section 1915(b) Waivers.--Case management may be provided in a waiver granted under §1915(b) of the Act. Section 1915(b) provides that a State may request that the Secretary waive the requirements of §1902 of the Act, including the freedom of choice requirements in §1902(a)(23), if necessary to implement a primary care case management system as described in 42 CFR 431.55(c).

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To qualify for such a waiver, the case management project must be cost effective, efficient, and consistent with the objectives of the Medicaid program. The waiver is needed to restrict the provider from (or through) whom an eligible individual can obtain medical care services (other than in emergency circumstances), provided the restriction does not substantially impair access to services of adequate quality, and that the statutory and regulatory requirements for waiver approvals are met. Upon the written request of the State, case management services furnished on or after April 7, 1986 pursuant to a waiver granted under §1915(b)(1) may be reimbursed at the FMAP rate when these services are performed by a vendor. Because of the nature of case management services under a §1915(b)(1) waiver, this activity, when performed by an employee of the Medicaid agency, is construed as necessary for the proper and efficient administration of the State plan and is therefore an administrative expense.

4. Section 1915(c) Waivers.--Case management may be provided as a service in a waiver granted pursuant to §1915(c) of the Act. Section 1915(c)(4)(B) specifically enumerates case management as a service which may be provided as part of a home and community-based services waiver. In order to provide this service, you must define it as part of a waiver request, and identify the qualifications of the providers. Under such a waiver, case management services must be provided under a written plan of care which is subject to the approval of the State Medicaid agency. Services provided in this fashion are reimbursed at the FMAP rate. Section 4440 supplies additional information concerning home and community-based services waivers.

NOTE: The enactment of P.L. 99-272 and P.L. 99-514 has not altered your authority to provide any of the previous categories of case management.

B. <u>Legislation</u>.--P.L. 99-272 adds case management to the list of optional services which may be provided under Medicaid. Section 9508 of P.L. 99-272 adds a new subsection (g) to §1915 of the Act. This subsection, as amended by P.L. 100-203, provides that:

"(g)(1) A State may provide, as medical assistance, case management services under the plan without regard to the requirements of section 1902(a)(1) and section 1902(a)(10)(B). The provision of case management services under this subsection shall not restrict the choice of the individual to receive medical assistance in violation of section 1902(a)(23). A State may limit the provision of case management services under this subsection to individuals with acquired immune deficiency syndrome (AIDS); or with AIDS-related conditions, or with either, and a State may limit the provision of case management services under this subsection to individuals with chronic mental illness. The State may limit the case managers available with respect to case management services for eligible individuals with developmental disabilities or with chronic mental illness in order to ensure that the case managers for such individuals are capable of ensuring that such individuals receive needed services.

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(2) For purposes of this subsection, the term 'case management services' means services which will assist individuals eligible under the plan in gaining access to needed medical, social, educational, and other services."

In authorizing States to offer case management services, Congress recognized that there was some potential for duplicate payments because the same or similar services have often been provided by other programs or under the Medicaid program itself. H. Rep. No. 453, 99th Cong., 1st Session 546 (1985), which accompanies this portion of P.L. 99-272, emphasizes that payment for case management services under §1915(g) must not duplicate payments made to public agencies or private entities under other program authorities for this same purpose.

FFP is available at the FMAP rate for targeted case management services rendered on or after April 7, 1986, when these services are included in the State plan.

- C. <u>Technical Statutory Change</u>.--Section 1895(c)(3) of the Tax Reform Act of 1986 adds case management services to §1905(a)(19) of the Act. In so doing, it defines §1905(a)(19) in terms of §1915(g)(2).
- D. <u>Purpose</u>.--The purpose of these instructions is to implement these sections of the statute, and to provide clarification regarding the requirements of the statute and how they may be met.
- 4302.1 <u>Case Management Services Process.--</u>
- A. Applicability.--The process described in this section applies to case management services, as described in §1905(a)(19) and §1915(g) of the Act.
- B. <u>Submission and Timeframes</u>.--Case management under either §1905(a)(19) or §1915(g) is an optional service under Medicaid. To provide the service, incorporate it into your Medicaid State Plan by means of a State plan amendment submitted to your servicing regional office. As with all State plan amendments that provide additional services, the effective date may be no earlier than the first day of the calendar quarter in which the amendment is submitted. In no case may FFP be claimed for case management services under §1915(g) provided prior to April 7, 1986.

In order to provide services under §1915(g), submit a separate amendment for each target group. There is no limit to the number or size of target groups to whom you may provide case management services. The target group may be the State's entire Medicaid population.

4302.2 <u>State Plan Amendment Requirements</u>.--Any State plan amendment request to provide optional case management services must address all of the requirements of this section.

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- A. <u>Target Group.</u>--Identify the target group to whom case management services will be provided. This targeting may be done by age, type or degree of disability, illness or condition (e.g., Acquired Immune Deficiency Syndrome (AIDS) or Chronic Mental Illness), or any other identifiable characteristic or combination thereof. The following examples are target groups currently receiving case management services under §1915(g) of the Act:
  - o Developmentally disabled persons (as defined by the State);
- o Children between the ages of birth and up to age 3 who are experiencing developmental delays or disorder behaviors as measured and verified by diagnostic instruments and procedures;
  - o Pregnant women and infants up to age 1;
  - o Individuals with hemophilia;
- o Individuals 60 years of age or older who have two or more physical or mental diagnoses which result in a need for two or more services; and
  - o Individuals with AIDS or HIV related disorders.

In defining the target group, you must be specific and delineate all characteristics of the population.

- B. <u>Comparability.</u>--Unless you intend to provide case management services in the same amount, duration and scope to all eligible recipients, indicate that §1915(g)(1) of the Act is invoked to provide these services without regard to the requirements of §1902(a)(10)(B) of the Act. (See 42 CFR 440.240.) The exception to comparability requirements applies only to case management services under §1915(g) of the Act. Comparability requirements relating to all other Medicaid services are unaffected by this section.
- C. Statewide Availability.--Indicate whether case management services are available to the target group statewide or whether the authority of §1915(g)(1) of the Act is invoked to provide case management services to the target group on a less than statewide basis. If case management services are not to be provided on a statewide basis, indicate the geographic areas or political subdivisions to be served. The provision of targeted case management services on a less than statewide basis does not excuse you from the requirements of §1902(a)(1) of the Act (see 42 CFR 431.50) in regard to the statewide availability of other Medicaid services.
- D. <u>Freedom of Choice.</u>--Section 1915(g)(1) of the Act specifies that there shall be no restriction on free choice of qualified providers, in violation of §1902(a)(23) of the Act. Assure that there will be no restriction on a recipient's free choice of qualified providers of case management services. In addition, assure that case management services will not restrict an individual's free choice of providers of other Medicaid services.

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In order to meet the freedom of choice requirements, you must provide for the following:

- 1. Option to Receive Services.--The receipt of case management services must be at the option of the individual included in the target population. A recipient cannot be forced to receive case management services for which he or she might be eligible.
- 2. Free Choice of Providers.--Except as indicated for individuals with developmental disabilities or chronic mental illness, an eligible individual must be free to receive case management services from any qualified provider of these services. The recipient may not be limited to case management providers in a clinic, even if the individual receives all other Medicaid services through that clinic. However, in situations where the State has chosen to provide case management services on a less than statewide basis, free choice of the qualified providers is limited to those providers located within all of the identified geographic areas or political subdivisions, as specified in the State plan.

When providing case management services to individuals with developmental disabilities or with chronic mental illness, you may limit the case managers available. This ensures that the case managers for these individuals are capable of providing the full range of needed services to these targeted recipients. This limitation is permissible <u>only</u> with regard to the target groups of developmentally disabled or chronically mentally ill, or any subgroups that you choose to define. If you choose to target a subgroup of individuals who are developmentally disabled or chronically mentally ill, the targeted group (e.g., based on age, degree of impairment) must continue to fit the definition of chronic mental illness or developmental disability. The requirements discussed in items D.1, D.3, and D.4 continue to apply to all target groups.

- 3. <u>Provider Participation</u>.--Any person or entity meeting State standards for the provision of case management services who wishes to become a Medicaid provider of those services must be given the opportunity to do so. However, the State is not required to extend provider participation to providers located outside the geographic areas in which case management is targeted.
- 4. <u>Unrestricted Access.</u>—Case management services under §1915(g) of the Act may not be used to restrict the access of the client to other services available under the State plan. This option is, however, available through waivers granted pursuant to §1915(b) of the Act. (See §2100.)
- E. Qualifications of Providers.--The statute does not set minimum standards for the provision of case management services. Therefore, establish the minimum qualifications for the providers of case management services. The qualifications set must be reasonably related to the case management functions that a provider is expected to perform. While reasonable provider qualifications are necessary to assure that case managers are capable of rendering services of acceptable quality, use caution in determining the acceptable degree of such qualifications. With the exception of providers of case management services to individuals with developmental disabilities or chronic mental illness, provider qualifications must not restrict the potential providers of case management services to only those viewed as most qualified. Individuals within the specified target group must be free to receive case management services from any qualified provider.

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Except as discussed in item D.2, you may not limit the provision of these services to State or other public agencies, but must permit any person or entity that meets the established qualifications in accordance with 42 CFR 431.51(b) to become a Medicaid provider.

F. <u>Nonduplication of Payments</u>.--Payment for case management services under §1915(g) of the Act may not duplicate payments made to public agencies or private entities under other program authorities for this same purpose.

In general, payment may not be made for services for which another payer is liable. Exceptions to this general rule include payments for prenatal or preventive pediatric care, including Early and Periodic Screening, Diagnostic and Treatment (EPSDT) services; payments for services covered under a plan for an individual for whom child support enforcement is being carried out; or any payments made through a waiver granted under the cost effectiveness provisions of 42 CFR 433.139(e). Another major exception is that payments may be made to State education agencies to cover the costs of services provided under a recipient's Individualized Education Program.

Payment may not be made for services for which no payment liability is incurred. Similarly, separate payment cannot be made for similar services which are an integral and inseparable part of another Medicaid covered service.

G. Differentiation Between Targeted Case Management Services and Case Management Type Activities for Which Administrative Federal Match May Be Claimed.--You must differentiate between case management services which may properly be claimed at the service match under \$1915(g) and case management activities which are appropriate for FFP at the administrative match under the State plan, based upon the appropriate criteria. These two payment authorities do not result in mutually exclusive types of services.

There are certain case management activities which may appropriately be eligible for FFP at either the administrative or the service match rate. Examples of case management activities that may be claimed at either the administrative or the service match rate entail providing assistance to individuals to gain access to services listed in the State plan, including medical care and transportation. In cases where an activity may qualify as either a Medicaid service or an administrative activity, you may classify the function in either category. This decision must be made prior to claiming FFP because of the different rules which apply to each type of function under the Medicaid program.

- 1. <u>Case Management as a Service Under §1915(g)</u>.--FFP is available at the FMAP rate for allowable case management services under §1915(g) when the following requirements are met:
- o Expenditures are made on behalf of eligible recipients included in the target group (i.e. there must be an identifiable charge related to an identifiable service provided to a recipient);
- o Case management services are provided as they are defined in the approved State plan;
- o Case management services are furnished by individuals or entities with whom the Medicaid agency has in effect a provider agreement;

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- o Case management services are furnished to assist an individual in gaining or coordinating access to needed services; and
- o Payment for services is made following the receipt of a valid provider claim. Providers must maintain case records which indicate all contacts with and on behalf of recipients. The case records must document name of recipient, the date of service, name of provider agency and person providing the service, nature, extent, or units of service, and the place of service delivery. In addition, providers must develop a billing system to appropriately identify and bill all liable third parties.

Because §1915(g) of the Act defines case management services as services which assist individuals eligible under the plan in gaining access to needed medical, social, educational, and other services, recipients may obtain access to services not included in the Medicaid State plan. The costs of case management services provided under §1915(g) that involve gaining access to non-Medicaid services are eligible for FFP at the service match rate.

Examples of case management services provided under §1915(g) of the Act may include assistance in obtaining Food Stamps, energy assistance, emergency housing, or legal services. All case management services provided as medical assistance pursuant to §1915(g) of the Act must be described in the State plan. In addition, they must be provided by a qualified provider as defined in the State plan.

When case management is provided pursuant to §1915(g) of the Act, the service is subject to the rules pertaining to all Medicaid services. If you choose to cover targeted case management services under your State plan, as defined in §1915(g) of the Act, you cannot claim FFP at the administrative rate for the same types of services furnished to the same target group.

NOTE: Although FFP may be available for case management activities that identify the specific services needed by an individual, assist recipients in gaining access to these services, and monitor to assure that needed services are received, FFP is not available for the cost of these specific services unless they are separately reimbursable under Medicaid. Also, FFP is not available for the cost of the administration of the services or programs to which recipients are referred.

- 2. <u>Case Management as an Administrative Activity</u>.--Case management activities may be considered allowable administrative costs of the Medicaid program when the following requirements are met:
- o They are provided in a manner consistent with simplicity of administration and the best interest of the recipient, as prescribed by §1902(a)(19) of the Act; and
- o Documentation maintained in support of the claim is sufficiently detailed to permit HCFA to determine whether the activities are necessary for the proper and efficient administration of the State plan, as provided by §1903(a) of the Act.

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The following list of functions provides examples of activities which may properly be claimed as administrative case management activities, but not as targeted case management services. The omission of any particular function from this list does not represent a determination on HCFA's part that the function is not necessary for the administration of the plan.

- o Medicaid eligibility determinations and redeterminations;
- Medicaid intake processing;
- o Medicaid preadmission screening for inpatient care;
- o Prior authorization for Medicaid services and utilization review; and
- o Medicaid outreach (methods to inform or persuade recipients or potential recipients to enter into care through the Medicaid system).

Because activities related to services which Medicaid does not cover are not considered necessary for the administration of the Medicaid plan, the accompanying costs are not eligible for Medicaid FFP at the administrative rate. For example, case management related to obtaining social services, Food Stamps, energy assistance, or housing cannot be considered a legitimate Medicaid administrative expense even though it may produce results which are in the best interest of the recipient. These services can be provided as medical assistance if described in the State plan.

Similarly, setting up an appointment with a Medicaid participating physician and arranging for transportation for a recipient may be considered case management administrative activities necessary for the proper and efficient administration of the Medicaid plan. However, arranging for baby sitting for a recipient's child, although beneficial to the recipient, is not an activity for which administrative FFP can be claimed.

In addition, when a caseworker suspects that physical abuse of a recipient has occurred, the referral to medical care could be considered a reimbursable administrative activity under the Medicaid program. However, assisting the victim in obtaining emergency housing and legal services, although in the best interest of the recipient, is not an activity for which administrative FFP may be claimed. In cases where workers perform activities funded under multiple auspices, careful records must be kept to document the State's claims for Federal funds under the appropriate authorities.

Administrative case management activities may be performed by an entity other than the single State agency. However, there must be an interagency agreement in effect.

When a State expects to claim FFP for Medicaid administrative case management activities, the costs for these activities must be included in a cost allocation plan submitted to and approved by your HCFA RO. HCFA reserves the right to evaluate the activities for which FFP is claimed to determine whether they meet the requirements (either administrative or service match) for payment. When FFP is claimed for any functions performed as case management administrative activities under §1903(a) of the Act, documentation must clearly demonstrate that the activities were provided to Medicaid applicants or eligibles, and were in some way connected with determining eligibility or administering services covered under the State plan.

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- H. Case Management Under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Program.--Care coordination, including aspects of case management, has always been an integral component of the EPSDT program, as described in 42 CFR 441.61. OBRA 1989 (P.L. 101-239) modified the EPSDT program by adding \$1905(r) to the Act. Section 1905(r) requires that States provide any services included in \$1905(a) of the Act, when medical necessity for the service is shown by an EPSDT screen, whether such services are covered under the State plan. While case management is required under the expanded EPSDT program when the need for the activity is found medically necessary, this does not mean \$1915(g) targeted case management services. Therefore, when the need for case management activities is found to be medically necessary, the State has several options to pursue:
- 1. <u>Component of an Existing Service</u>.--Case management services may be provided to persons participating in the EPSDT program by an existing service provider such as a physician or clinic referring the child to a specialist.
- 2. Administration.-Case management services may be provided to EPSDT participants by the Medicaid agency or another State agency such as title V, the Health Department or an entity with which the Medicaid agency has an interagency agreement. Administrative case management activities must be found necessary for the proper and efficient administration of the State plan and therefore must be limited to those activities necessary for the proper and efficient administration of Medicaid covered services. FFP is available at the administrative rate.
- 3. <u>Medical Assistance.</u>—Case management services may be provided under the authority of §1905(a)(19) of the Act. The service must meet the statutory definition of case management services, as defined by §1915(g) of the Act. Therefore, FFP is available for assisting recipients in gaining access to both Medicaid and non-Medicaid services. FFP for case management services furnished under §1905(a)(19) of the Act is available at the FMAP rate.

Any combination of two or more of the above is possible, as long as FFP is not available for duplication of services.

- I. <u>Service Limitations</u>.--The following are not allowable targeted case management services as defined in §1915(g)(2) of the Act.
- 1. Other Medicaid Services.--When assessing an individual's need for services includes a physical or psychological examination or evaluation, bill for the examination or evaluation under the appropriate medical service category. Referral for such services may be considered a component of case management services, but the actual provision of the service does not constitute case management.
- 2. <u>Referral for Treatment.</u>—When an assessment indicates the need for medical treatment, referral or arrangements for such treatment may be included as case management services, but the actual treatment may not be considered.
- 3. <u>Institutional Discharge Planning</u>.--Discharge planning is required as a condition for payment of hospital, NF and ICF/MR services. Therefore, this cannot be billed separately as a targeted case management service.

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- 4. <u>Client Outreach</u>.--Outreach activities in which a State agency or a provider attempts to contact potential recipients of a service do not constitute case management services. The statute defines case management services as, "services which will assist individuals <u>eligible under the plan</u> in gaining access to needed medical, social, educational and other services" (emphasis added). The attempt to contact individuals who may or may not be eligible for case management services does not fall under this definition. However, such outreach activities may be considered necessary for the proper and efficient administration of the Medicaid State plan. When this is the case, FFP is available at the administrative rate.
- J. Coordination With Home and Community-Based Services Waivers.--Case management services continue to be available under home and community-based services waivers approved pursuant to §1915(c) of the Act. However, since approval for §1915(c) waiver services may only be granted for services not otherwise available under the State plan, the addition of case management services under the State plan may necessitate the modification of a home and community-based services waiver. In order to comply with the nonduplication of services requirements discussed in §4302B, the following elements apply to waivers under §1915(c).
- 1. <u>Service Not Included in Waiver</u>.--Home and community-based services waivers (and requests for waivers) which do not contain case management as a waiver service are not affected by this section.
- 2. <u>Different Target Population</u>.--Home and community-based services waivers (and requests for waivers) which are targeted at a population different from the group(s) to whom targeted case management services are provided are not affected by this section.
- 3. <u>Duplication of State Plan Service</u>.--When a home and community-based services waiver contains case management as a waiver service and the State adds case management services to the State plan, the following apply:
- a. <u>Same Target Population and Service Definition</u>.--If the target population <u>and</u> the service definitions are the same, delete the case management services from the waiver through an amendment request, and make appropriate cost and utilization adjustments to the waiver cost effectiveness formula.
- b. <u>Same Service Definition</u>.--If the definition of services is the same, but only a portion of waiver recipients (who receive waiver case management) are now eligible for the State plan service, the service may remain in the waiver. Adjustments must be made to the cost effectiveness formula to reflect the fact that a number of recipients now receive the State plan service.
- 4. <u>Same Target Population</u>.--If you have targeted case management services in your State plan for a particular group, and you submit a waiver request for the same targeted group, the request for waiver may not include case management services through the waiver under the same definition used in the State plan. If the case management is provided under an identical definition, it must be provided under the State plan and not under the waiver.

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- K. <u>Payment Methodology</u>.--The amendment must specify the methodology by which payments and rates are made. Indicate the payment methodology for public as well as private providers. Enter this information on attachment 4.19-B of the State plan.
- L. <u>Documentation of Claims for Case Management Services.</u>—In order to receive payment for case management services under the plan (i.e., at the FMAP rate), fully document your claim as you do for any other Medicaid service. If you pay for case management services through capitation or prepaid health plans, the requirements of 42 CFR Part 434 must be met. With the exception of claims paid under capitation or prepaid health plan arrangements, you must document the following:
  - o date of service,
  - o name of recipient,
  - o name of provider agency and person providing the service,
  - o nature, extent, or units of service, and
  - o place of service.

NOTE: While forms of documentation such as time studies, random moment sampling and cost allocation plans may be appropriate for claiming administrative FFP for activities in support of the State plan, these modes of documentation are not acceptable as a basis for Federal participation in the costs of Medicaid services. There must be an identifiable charge related to an identifiable service provided to a recipient.

# 4302.3 Instructions For Completing Preprint Supplement.--

- A. <u>State Plan Amendment.</u>—To include case management services in your State plan, indicate your intentions on Attachment 3.1-A and 3.1-B of the State plan preprint. In addition, complete one preprint supplement for each target group to whom the services will be provided. (OMB approval is required under the Paper Work Reduction Act of 1980 and will be obtained.)
- B. <u>Supplement 1 to Attachment 3.1-A</u>.--Exhibit 1 is a copy of supplement 1 to Attachment 3.1-A. Each item must be completed for the amendment to be approved.
- Item 1. Define the target group. Indicate any limitations of disease or condition, age, institutional or noninstitutional status or other characteristic(s) by which the target group is identified.
- Item 2. Check one category. If services are provided on a less than statewide basis, specify the geographic areas or political subdivisions to which the services will be provided.
  - Item 3. Check one category.
- Item 4. Define case management services as they apply to the target population. Specify any limitations that apply. Indicate the unit(s) of service. Identify any coordination with non-Medicaid programs or agencies.

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Item 5. Specify the qualifications of the providers. These qualifications must be reasonably related to the case management function(s) that the providers are expected to perform.

Item 6. No information necessary.

Item 7. No information necessary.

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# **EXHIBIT I**

	STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
State/Terr	ritory:
	CASE MANAGEMENT SERVICES
A.	Target Group:
В.	Areas of State in Which Services Will Be Provided:
	Entire State
to provide	Only in the following geographic areas (authority of $\S1915(g)(1)$ of the Act is invoked exervices less than statewide):
C.	Comparability of Services:
C.	Services are provided in accordance with §1902(a)(10)(B) of the Act.
of the Act	Services are not comparable in amount, duration and scope. Authority of §1915(g)(1) is invoked to provide services without regard to the requirements of §1902(a)(10)(B).
D.	Definition of Services:
E.	Qualifications of Providers:
F.	The State assures that the provision of case management services will not restrict an

1. Eligible recipients will have free choice of the providers of case management services.

individual's free choice of providers in violation of §1902(a)(23) of the Act.

- 2. Eligible recipients will have free choice of the providers of other medical care under the plan.
- G. Payment for case management services under the plan shall not duplicate payments made to public agencies or private entities under other program authorities for this same purpose.

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#### 4305. HOSPICE SERVICES

Hospice care is an optional benefit under the Medicaid program. A hospice is a public agency or private organization or a subdivision of either that is primarily engaged in providing care to terminally ill individuals. A participating hospice meets the Medicare conditions of participation for hospices and has a valid provider agreement. Hospice coverage must be available for at least 210 days and may be subdivided into two or more periods at State option. (The Medicare benefit is divided into two 90 day periods and one 30 day period.)

In order to be eligible to elect hospice care under Medicaid, an individual must be certified as being terminally ill. An individual is considered to be terminally ill if the individual has a medical prognosis that his or her life expectancy is six months or less.

- 4305.1 <u>Physician Certification</u>.--The hospice must obtain the certification that an individual is terminally ill in accordance with the following procedures:
- o For the first period of hospice coverage, the hospice must obtain, no later than two calendar days after hospice care is initiated, written certification statements signed by the medical director of the hospice or the physician member of the hospice interdisciplinary group and the individual's attending physician (if the individual has an attending physician).

If the hospice does not obtain a written certification within two days after the initiation of hospice care, a verbal certification may be obtained within these 2 days, and a written certification obtained no later than 8 days after care is initiated. If these requirements are not met, no payment can be made for days prior to the certification. The attending physician is a physician who is a doctor of medicine or osteopathy and is identified by the individual at the time he or she elects to receive hospice care as having the most significant role in the determination and delivery of the individual's medical care.

- o For any subsequent period, the hospice must obtain, no later than two calendar days after the beginning of that period, a written certification statement prepared by the medical director of the hospice or the physician member of the hospice's interdisciplinary group. The certification must include the statement that the individual's medical prognosis is that his or her life expectancy is six months or less if the terminal illness runs its normal course and the signature(s) of the physician(s). The hospice must retain the certification statements.
- 4305.2 <u>Election Procedures.</u>—If an individual elects to receive hospice care, he or she must file an election statement with a particular hospice. An election may also be filed by a representative acting pursuant to State law. With respect to an individual granted the power of attorney for the patient, State law determines the extent to which the individual may act on the patient's behalf.

An election to receive hospice care is considered to continue through the initial election period and through any subsequent election periods without a break in care as long as the individual remains in the care of the hospice and does not revoke the election. An individual may designate an effective date for the election period that begins with the first day of hospice care or any subsequent day of hospice care, but an individual may not designate an effective date that is earlier than the date that the election is made.

For purposes of the Medicaid hospice benefit, a nursing facility may be considered the residence of a beneficiary. A beneficiary residing in such a setting may elect the hospice benefit. An addition to hospice reimbursement is made in this situation to take the room and board provided by the facility into account. (See §4308.2). The hospice reimburses the facility for these services.

An individual must waive all rights to Medicaid payments for the duration of the election of hospice care for the following services:

- o Hospice care provided by a hospice other than the hospice designated by the individual (unless provided under arrangements made by the designated hospice); and
- o Any Medicaid services that are related to the treatment of the terminal condition for which hospice care was elected or a related condition or that are equivalent to hospice care except for services--
  - Provided (either directly or under arrangement) by the designated hospice;
- Provided by the individual's attending physician if that physician is not an employee of the designated hospice or receiving compensation from the hospice for those services; or
  - Provided as room and board by a nursing facility if the individual is a resident.

After the hospice benefit expires, the patient's waiver of these other Medicaid benefits expires and coverage of certain services provided through the hospice may be possible. For example, if the hospice must provide acute inpatient care in a hospital with which it has an agreement, the hospital could bill Medicaid for covered hospital services.

- 4305.3 <u>Election, Revocation and Change of Hospice</u>.--The election statement must include the following items of information:
  - o Identification of the particular hospice that will provide care to the individual;
- o The individual's or representative's acknowledgement that he or she has been given a full understanding of hospice care;

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- o The individual's or representative's acknowledgement that he or she understands that the Medicaid services listed in §4305.2 are waived by the election;
  - o The effective date of the election; and
  - o The signature of the individual or representative.

An individual or representative may revoke the election of hospice care at any time. To revoke the election of hospice care, the individual must file a document with the hospice that includes a signed statement that the individual revokes the election for Medicaid coverage of hospice care and the date that the revocation is to be effective. The individual forfeits coverage for any remaining days in that election period if the benefit is broken into periods. If it is not or no periods are left, the revocation is permanent. An individual may not designate an effective date earlier than the date that the revocation is made.

Upon revoking the election of Medicaid coverage of hospice care for a particular election period, an individual resumes Medicaid coverage of the benefits waived when hospice care was elected. An individual may at any time elect to receive hospice coverage for any other hospice election periods for which he or she is eligible.

An individual may change, once in each election period, the designation of the particular hospice from which he or she elects to receive hospice care. The change of the designated hospice is not considered a revocation of the election. To change the designation of hospice programs, the individual must file, with the hospice from which he or she has received care and with the newly designated hospice, a signed statement that includes the following information: the name of the hospice from which the individual has received care, the name of the hospice from which he or she plans to receive care and the date the change is effective. A change of ownership of a hospice is not considered a change in the patient's designation of a hospice, and requires no action on the patient's part.

If an individual is eligible for Medicare as well as Medicaid, the hospice benefit must be elected and revoked simultaneously under both programs if the State offers the benefit.

4305.4 Requirements for Coverage.--To be covered, a certification that the individual is terminally ill must have been completed as set forth in §4305.1, and hospice services must be reasonable and necessary for the palliation or management of the terminal illness and related conditions. The individual must elect hospice care in accordance with §4305.2, and a plan of care must be established before services are provided. To be covered, services must be consistent with the plan of care.

In establishing the initial plan of care, the member of the basic interdisciplinary group who assesses the patient's needs must meet or call at least one other group member (nurse, physician, medical social worker or counselor) before writing the initial plan of care.

At least one of the persons involved in developing the initial plan must be a nurse or physician. This plan must be established on the same day as the assessment if the day of assessment is to be a covered day of hospice care. The other two members of the basic interdisciplinary group must review the initial plan of care and provide their input to the process of establishing the plan of care within two calendar days following the day of assessment.

- 4305.5 <u>Covered Services.</u>—All services must be performed by appropriately qualified personnel, but it is the nature of the service, rather than the qualification of the person who provides it, that determines the coverage category of the service. The following services are covered hospice services:
  - o Nursing care provided by or under the supervision of a registered nurse.
- o Medical social services provided by a social worker who has at least a bachelor's degree from a school accredited or approved by the Council on Social Work Education, and who is working under the direction of a physician.
- o Physicians' services performed by a physician (as defined in 42 CFR 410.20) except that the services of the hospice medical director or the physician member of the interdisciplinary group must be performed by a doctor of medicine or osteopathy.
- o Counseling services provided to the terminally ill individual and the family members or other persons caring for the individual at home. Counseling, including dietary counseling, may be provided both for the purpose of training the individual's family or other care-giver to provide care, and for the purpose of helping the individual and those caring for him or her to adjust to the individual's approaching death.
- o Short-term inpatient care provided in a participating hospice inpatient unit, or a participating hospital or nursing facility that additionally meets the special hospice standards regarding staffing and patient areas. Services provided in an inpatient setting must conform to the written plan of care. General inpatient care may be required for procedures necessary for pain control or acute or chronic symptom management which cannot be provided in other settings. Inpatient care may also be furnished to provide respite for the individual's family or other persons caring for the individual at home.
- o Medical appliances and supplies, including drugs and biologicals. Only drugs as defined in §1861(t) of the Act and which are used primarily for the relief of pain and symptom control related to the individual's terminal illness are covered. Appliances may include covered durable medical equipment as well as other self-help and personal comfort items related to the palliation or management of the patient's terminal illness. Equipment is provided by the hospice for use in the patient's home while he or she is under hospice care. Medical supplies include those that are part of the written plan of care.

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- o Home health aide services furnished by qualified aides and homemaker services. Home health aides may provide personal care services. Aides may also perform household services to maintain a safe and sanitary environment in areas of the home used by the patient, such as changing the bed or light cleaning and laundering essential to the comfort and cleanliness of the patient. Aide services must be provided under the general supervision of a registered nurse. Homemaker services may include assistance in personal care, maintenance of a safe and healthy environment and services to enable the individual to carry out the plan of care.
- o Physical therapy, occupational therapy and speech-language pathology services provided for purposes of symptom control or to enable the individual to maintain activities of daily living and basic functional skills.

Nursing care, physicians' services, medical social services and counseling are core hospice services and must routinely be provided directly by hospice employees. Supplemental services may be contracted for during periods of peak patient loads and to obtain physician specialty services.

4305.6 Special Coverage Requirements.--Continuous home care is to be provided only during a period of crisis. A period of crisis is a period in which a patient requires continuous care which is primarily nursing care to achieve palliation or management of acute medical symptoms. Nursing care must be provided by either a registered nurse or a licensed practical nurse and a nurse must be providing care for more than half of the period of care. A minimum of 8 hours of care must be provided during a 24-hour day which begins and ends at midnight. This care need not be continuous, i.e., 4 hours could be provided in the morning and another 4 hours provided in the evening of that day. Homemaker and aide services may also be provided to supplement the nursing care. Continuous home care is covered when it is provided to maintain an individual at home during a medical crisis. If less skilled care is needed on a continuous basis to enable the person to remain at home, this is covered as routine home care.

Respite care is short-term inpatient care provided to the individual only when necessary to relieve the family members or other persons caring for the individual at home. Respite care may be provided only on an occasional basis and may not be reimbursed for more than five consecutive days at a time. Respite care may not be provided when the hospice patient is a nursing home resident.

Bereavement counseling consists of counseling services provided to the individual's family after the individual's death. Bereavement counseling is a required hospice service but it is not reimbursable.

#### 4306. HOSPICE REIMBURSEMENT

With the exception of payment for physician services (see §4307) Medicaid payment for hospice care is made at one of four predetermined rates for each day in which an individual is under the care of the hospice. Establish rates no lower than the rates used under Part A of title XVIII (Medicare), adjusted to disregard cost offsets attributable to Medicare coinsurance amounts, using the same methodology used under Part A. The four rates are prospective rates. There are no retroactive adjustments other than the optional application of the "cap" on overall payments and the limitation on payments for inpatient care, if applicable. The rate paid for any particular day varies depending on the level of care furnished to the individual. The "cap" and the limitations on payment for inpatient care are described in sections that follow.

- 4306.1 <u>Levels of Care</u>.--There are four levels of care into which each day of care is classified:
  - o Routine Home Care,
  - o Continuous Home Care,
  - o Inpatient Respite Care, or
  - o General Inpatient Care

For each day that an individual is under the care of a hospice, pay the hospice an amount applicable to the type and intensity of the services furnished to the individual for that day. For continuous home care, the amount of payment is determined based on the number of hours of continuous care furnished to the beneficiary on that day. A description of each level of care follows.

- A. <u>Routine Home Care.</u>—Pay the hospice the routine home care rate for each day the patient is under the care of the hospice and you do not pay at another rate. This rate is paid without regard to the volume or intensity of services provided on any given day.
- B. <u>Continuous Home Care.</u>--Pay the hospice at the continuous home care rate when continuous home care is provided. (See §4305.6.) The continuous home care rate is divided by 24 hours in order to arrive at an hourly rate. A minimum of 8 hours per day must be provided. Pay the hospice for every hour or part of an hour of continuous care furnished up to a maximum of 24 hours a day.
- C. <u>Inpatient Respite Care.</u>--Pay the hospice at the inpatient respite care rate for each day on which the beneficiary is in an approved inpatient facility and is receiving respite care. (See §4305.6.) Pay for respite care for a maximum of 5 days at a time including the date of admission but not counting the date of discharge. Pay for the sixth and any subsequent days at the routine home care rate.
- D. <u>General Inpatient Care.</u>--Pay at the general inpatient rate when general inpatient care is provided except as described in §4306.2.

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4306.2 <u>Date of Discharge</u>.--For the day of discharge from an inpatient unit, pay the appropriate home care rate unless the patient dies as an inpatient. When the patient is discharged deceased, the inpatient rate (general or respite) is paid for the discharge date.

4306.3 <u>Hospice Payment Rates.</u>—The minimum national Medicaid hospice rates, before area wage adjustments for each of the categories of care described in §4306.1 are:

Routine Home Care Rate	\$ 79.85	
Continuous Home Care Rates	465.57	Full Rate-24 hours of care
	19.40	Hourly Rate
Inpatient Respite Care Rate	86.82	•
General Inpatient Care Rate	354.73	

These rates are based on the methodology used in setting Medicare rates, adjusted to disregard cost offsets attributable to Medicare coinsurance amounts. Under the Medicaid hospice benefit, no cost sharing may be imposed with respect to hospice services rendered to Medicaid recipients. These rates are in effect for services provided on or after January 1, 1990.

Effective on or after April 1, 1990, the State may choose to establish hospice payment rates at higher amounts than those listed above. In no case may hospice payment amounts be established in amounts lower than the amounts listed above.

4306.4 Local Adjustment of Payment Rates.--The payment rates in §4306.3 are adjusted for regional differences in wages, using indices published in Addenda A and B. To select the proper index for an area, first determine if the hospice is located in one of the Urban Areas listed in Addendum A. If so, use the index for that area. If the hospice is not listed as one of the Urban Areas in Addendum A, use the index number of the rural area for the State listed in Addendum B. If the index number for the applicable area is less than 0.8, use 0.8 as the index. Once the appropriate index figure is determined, the computation of the rates for a hospice can be made using the methodology contained in the following tables in this section. Table I indicates the portion of each of the minimum national hospice Medicaid rates subject to the wage index. Table II is an example of the computation of wage adjusted rates for a hospice located in Baltimore, Maryland, using the minimum national Medicaid rates and the applicable index number of 1.0860. Table III is used to compute the rates applicable to a particular hospice. The wage adjusted continuous care rate is then divided by 24 to determine the hourly billing rate.

# TABLE I

	Minimum National Medicaid Rates	Wage component subject to index	Unweighted amount
Routine Home Care	\$79.85 (100%)	\$54.87 (68.71%)	\$24.98 (31.29%)
Continuous Home Care	465.57 (100%)	319.89 (68.71%)	145.68(31.29%)
Inpatient Respite	86.82 (100%)	47.00 (54.12%)	39.82(45.88%)
General Inpatient Care	354.73 (100%)	227.06 (64.02%)	127.67(35.98%)

# TABLE II

	Minimum National Medicaid Rates	Wage Compo- nent subject to index	Index for Balt. MD	Adjusted Wage Component	Non-wage Component	Adj. Rate
Routine Home Care	\$79.85	\$54.87	1.0860	\$59.59	\$24.98	\$84.57
Continous Home Care	465.57	319.89	1.0860	347.40	145.68	493.08
Inpatient Respite	86.82	47.00	1.0860	51.04	39.82	90.86
General Inpatient Care	354.73	227.06	1.0860	246.59	127.67	374.26

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#### TABLE III

	State Estab- lished Medicaid Rates col 1	Wage component subject to index (Multiply applicable percentage from Table 1 by col. 1 col 2	Index for your area* col 3	Adjusted wage component (col. 2 x col. 3) col 4	Non-wage component (Multiply applicable percentage from Table 1 by col. 1 col 5	Wage Adjusted Rates for your area (col. 4 + col. 5) col 6
Routine Home Care Continuous Home Care						
Inpatient Respite General Inpatient Care						

Continuous Home Care Rate, adjusted for wages = \$:- 24 hours = \$ \_\_\_\_ Hourly Rate

4306.5 Limitation on Payments for Inpatient Care.--Payments to a hospice for inpatient care must be limited according to the number of days of inpatient care furnished to Medicaid patients. During the 12-month period beginning November 1 of each year and ending October 31, the aggregate number of inpatient days (both for general inpatient care and inpatient respite care) may not exceed 20 percent of the aggregate total number of days of hospice care provided to all Medicaid recipients during that same period. The State may exclude Medicaid recipients afflicted with acquired immunodeficiency syndrome (AIDS) in calculating this inpatient care limitation. This limitation is applied once each year, at the end of the hospices' "cap period" (11/1 -10/31). For purposes of this computation, if it is determined that the inpatient rate should not be paid, any days for which the hospice receives payment at a home care rate are not counted as inpatient days. Calculate the limitation as follows:

- o The maximum allowable number of inpatient days is calculated by multiplying the total number of days of Medicaid hospice care by 0.2.
- o If the total number of days of inpatient care furnished to Medicaid hospice patients is less than or equal to the maximum, no adjustment is necessary.

<sup>\*</sup> If index for an area is less than 0.8, use 0.8.

- o If the total number of days of inpatient care exceeded the maximum allowable number, the limitation is determined by:
- 1. calculating a ratio of the maximum allowable days to the number of actual days of inpatient care, and multiplying this ratio by the total reimbursement for inpatient care (general inpatient and inpatient respite reimbursement) that was made,
  - 2. multiplying excess inpatient care days by the routine home care rate,
  - 3. adding together the amounts calculated in 1 and 2, and
- 4. comparing the amount in 3 with interim payments made to the hospice for inpatient care during the "cap period."

Any excess reimbursement is refunded by the hospice.

## 4307. PAYMENT FOR PHYSICIAN SERVICES UNDER HOSPICE

The basic payment rates for hospice care which are listed in Table I are designed to reimburse the hospice for the costs of all covered services related to the treatment of the beneficiary's terminal illness, including the administrative and general supervisory activities performed by physicians who are employees of or working under arrangements made with the hospice. These activities are generally performed by the physician serving as the medical director and the physician member of the hospice interdisciplinary group. Group activities include participation in the establishment of plans of care, supervision of care and services, periodic review and updating of plans of care, and establishment of governing policies. The costs for these services are included in the reimbursement rates for routine home care, continuous home care, and inpatient respite care.

Pay the hospice for other physicians' services, such as direct patient care services, furnished to individual patients by hospice employees and for physician services furnished under arrangements made by the hospice unless the patient care services were furnished on a volunteer basis. At your option, the hospice may be reimbursed in accordance with the usual Medicaid reimbursement policy for physicians services contained in 42 CFR 447ff or in accordance with the Medicare methodology for payment of hospice physician services. This reimbursement is in addition to the daily rates. Total payments made to the hospice for these services are counted, along with total payments made at the various hospice daily rates, in determining whether the optional hospice cap amount has been exceeded.

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Physicians who are designated by recipients as the attending physician and who also volunteer services to the hospice are, as a result of their volunteer status, considered employees of the hospice in accordance with 42 CFR 418.3. (This enables the hospice to use volunteers to meet the physician core service requirement in 42 CFR 418.80.) All

direct patient care services rendered by these physicians to hospice patients are hospice physician services, and are reimbursed in accordance with the procedures outlined in the preceding paragraph. As stated in the preceding paragraph, physician services furnished on a volunteer basis are excluded from Medicaid reimbursement. You may reimburse the hospice on behalf of a volunteer physician for specific services rendered which are not furnished on a volunteer basis (a physician may seek reimbursement for some services while furnishing other services on a volunteer basis). The hospice must have a liability to reimburse the physician for those physician services rendered. In determining which services are furnished on a volunteer basis and which services are not, a physician must treat Medicaid patients on the same basis as other patients in the hospice. For instance, a physician may not designate all physician services rendered to non-Medicaid patients as volunteered and at the same time seek payment from the hospice for all physician services rendered to Medicaid patients.

**EXAMPLE:** 

Dr. Jones has an agreement with a hospice to serve as its medical director on a volunteer basis. Mrs. Smith, a Medicaid recipient, enters this hospice and designates Dr. Jones as her attending physician. Dr. Jones, who does not furnish direct patient care services on a volunteer basis, renders a direct patient care service to Mrs. Smith. Dr. Jones seeks reimbursement from the hospice for this service. The hospice is then paid by the State agency in accordance with the usual payment rules for Medicaid physician services for the specific service Dr. Jones rendered to Mrs. Smith. The hospice then reimburses Dr. Jones for this service. Dr. Jones, by virtue of his volunteer activities, is deemed to be an employee of the hospice in accordance with 42 CFR 418.3. Accordingly, such services are included in determining whether the optional Medicaid cap amount has been exceeded.

The hospice notifies you of the election and the name of the physician who has been designated as the attending physician whenever the attending physician is not a hospice employee. Reimburse an independent attending physician in accordance with the usual Medicaid reimbursement methodology for physician services contained in 42 CFR 447ff. These services are <u>not</u> counted in determining whether the optional hospice cap amount has been exceeded. This is because these services of an independent attending physician are not part of the hospice's care. Note that the only services billed by the attending physician are the physician's personal professional services. Costs for services such as lab or X-rays are not included on the attending physician's bill.

#### 4308. OPTIONAL CAP ON OVERALL HOSPICE REIMBURSEMENT

You may limit overall aggregate payments made to a hospice during a hospice cap period. The cap period runs from November 1st of each year through October 31 of the next year. The total payment made for services furnished to Medicaid beneficiaries during this period is compared to the "cap amount" for this period. Any payments in excess of the cap must be refunded by the hospice. This limit is based on services rendered during the cap year regardless of when payment is actually made. Payments are measured in terms of all payments made to hospices on behalf of all Medicaid hospice beneficiaries receiving services during the cap year, regardless of the year in which the beneficiary is counted in determining the cap. For example, payments made to a hospice for an individual electing hospice care on October 5, 1989, pertaining to services rendered in the cap year beginning November 1, 1988, and ending October 31, 1989, are counted as payments made during the first cap year (November 1, 1988 - October 31, 1989), even though that individual is not counted in the calculation of the cap for that year. (The individual is counted in the cap calculation for the following year since the election occurred after September 27 -see below).

The hospice cap is calculated in a different manner for new hospices entering the program if the hospice has not participated in the program for an entire cap year. In this situation, we require that the initial cap calculations for newly certified hospices cover a period of at least 12 months but not more than 23 months. For example, the first cap period for a hospice entering the program on October 1, 1989, runs from October 1, 1989 through October 31, 1990. Similarly, the first cap period for hospice providers entering the program after November 1, 1988 but before November 1, 1989 ends October 31, 1990.

The cap amount is calculated by multiplying the number of beneficiaries electing hospice care during the period by the current cap amount. This amount is adjusted annually to reflect the percentage increase or decrease in the medical care expenditure category of the Consumer Price Index (CPI) for all urban consumers (U.S. city average), published by the Bureau of Labor Statistics (BLS), from March 1984 to the fifth month of the accounting year. Section 4308.1 explains how the original statutory cap amount of \$6,500 is adjusted.

The computation and application of the cap amount is made by the State at the end of the cap period. The hospice is responsible for reporting the number of Medicaid recipients electing hospice care during the period to the State. This must be done within 30 days after the end of the cap period.

The hospice must adhere to the following rules in determining the number of Medicaid beneficiaries who have elected hospice care during the period:

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- o The beneficiary must not have been counted previously in either another hospice's cap or another reporting year; and
- o The beneficiary must have filed an initial election during the period beginning September 28 of the previous cap year through September 27 of the current cap year to be counted as an electing Medicaid beneficiary during the current cap year.

Once a beneficiary has been included in the calculation of a hospice cap amount he or she may not be included in the cap for that hospice again, even if the number of covered days in a subsequent reporting period exceeds that of the period where the beneficiary was included. (This could occur when the beneficiary has breaks between periods of election.)

When a beneficiary elects to receive hospice benefits from two or more different Medicaid certified hospices, proportional application of the cap amount is necessary. A calculation must be made by the State to determine the percentage of the patient's length of stay in each hospice relative to the total length of hospice stay.

EXAMPLE: John Doe, a Medicaid beneficiary, initially elects hospice care from Hospice A on September 2, 1989. Mr. Doe stays in Hospice A until October 2, 1989 (30 days) at which time he changes his election and enters Hospice B.

Mr. Doe stays in Hospice B for 70 days until his death on December 11, 1989. The State determines that the total length of hospice stay for Mr. Doe is 100 days (30 days in Hospice A and 70 days in Hospice B). Since Mr. Doe was in Hospice A for 30 days, Hospice A counts .3 of a Medicaid beneficiary for Mr. Doe in its hospice cap calculation (30 days -: 100 days). Hospice B counts .7 of a Medicaid beneficiary in its cap calculation (70 days -: 100 days).

Readjustment of the hospice cap may be required if information previously unavailable to the State at the time the hospice cap is applied subsequently becomes available.

EXAMPLE: Using the example above, if the State had calculated and applied the hospice cap on November 30, 1989, information was not available at that time to adjust the number of beneficiaries reported by Hospice A, since Mr. Doe did not die until December 11, 1989. The State recalculates the hospice cap to Hospice A based on the information it later receives. The cap for Hospice A after recalculation reflects the proper beneficiary count of .3 for Mr. Doe. The cap for Hospice B reflects the proper beneficiary count of .7 for Mr. Doe.

An additional step is required when more than one Medicaid certified hospice provides care to the same individual, and the care overlaps 2 cap years. In this case, the State must determine in which cap year the fraction of a beneficiary is reported. If the

beneficiary entered the hospice before September 28, the fractional beneficiary is included in the current cap year. If the beneficiary entered the hospice after September 27, the fractional beneficiary is included in the following cap year.

EXAMPLE: Continuing with the case cited in the examples above, Hospice A includes .3 of a Medicaid beneficiary in its cap calculation for the cap year beginning November 1, 1988, and ending October 31, 1989, since Mr. Doe entered Hospice A before September 28, 1989. Hospice B includes .7 of a Medicaid beneficiary in its cap calculation for the cap year beginning November 1, 1989, and ending October 31, 1990, since Mr. Doe entered Hospice B after September 27, 1989.

Where services are rendered by two different hospices to a Medicaid patient, and one of the hospices is not certified by Medicaid, no proportional application is necessary. Count one patient and use the total cap for the certified hospice.

4308.1 Adjustments to Cap Amount.--The original cap amount of \$6,500 per year increases or decreases for accounting years that end after October 1, 1984 by the same percentage as the percentage of increase or decrease in the medical care expenditure category of the consumer price index for all urban consumers (United States city average), published by the Bureau of Labor Statistics, from March 1984 to the fifth month of the accounting year. As indicated in 42 CFR 418.309, the hospice cap is applied on the basis of a cap year beginning November 1 and ending the following October 31.

No inflation adjustment was needed to the \$6,500 cap in the first cap year, since the fifth month of the accounting year was March 1984. (See table below.) Index numbers are published in this section when they become available to update the statutory amount of \$6,500. The index periods for use in updating the hospice cap amount are as follows:

	INDEX PERIOD	INDEX NUMBER	HOSPICE CAP
1st Cap Year 2nd Cap Year 3rd Cap Year 4th Cap Year 5th Cap Year 6th Cap Year	March 1984 to March 1984 March 1984 to March 1985 March 1984 to March 1986 March 1984 to March 1987 March 1984 to March 1988 March 1984 to March 1989	1.00 1.059 1.137 1.2150 1.2932 1.3861	\$6,500 \$6,884 \$7,391 \$7,898 \$8,406 \$9,010
7th Cap Year	March 1984 to March 1990	1.5057	\$9,787

The cap amount for the second and subsequent cap years is calculated by multiplying \$6,500 by the applicable index number.

In those situations where a hospice begins participation in Medicaid at any time other than the beginning of a cap year (November 1st), and hence has an initial cap calculation for a period in excess of 12 months, a weighted average cap amount is used. The following example illustrates how this is done.

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EXAMPLE: 10/01/84 - Hospice A is Medicaid Certified.

10/01/84 to 10/31/85 - First cap period (13 months) for Hospice A. Statutory cap for first cap year (11/01/83 - 10/31/84) = \$6,500 Statutory cap for second cap year (11/01/84 - 10/31/85) = \$6,884 Weighted average cap calculation for Hospice A:

Weighted average cap calculation for Hospice A: One month (10/01/84 - 10/31/84) at \$6,500 = \$6,500 12 months (11/01/84 - 10/31/85) at \$6,884 = \$82,608 13 month period \$89,108 divided by 13 = \$6,854 (rounded)

In this example, \$6,854 is the weighted average cap amount used in the initial cap calculation for Hospice A for the period October 1, 1984 through October 31, 1985.

NOTE: If Hospice A had been certified in mid-month, a weighted average cap amount based on the number of days falling within each cap period is used.

4308.2 Additional Amount for Nursing Facility Residents.--When hospice care is furnished to an individual residing in a nursing facility, pay the hospice an additional amount on routine home care and continuous home care days to take into account the room and board furnished by the facility. This amount is determined in accordance with the rates established under §1902(a)(13) of the Act. The additional amount paid to the hospice on behalf of an individual residing in a nursing facility must equal at least 95 percent of the per diem rate that you would have paid to the nursing facility for that individual in that facility under your State plan. In this context, the term "room and board" includes performance of personal care services, including assistance in the activities of daily living, in socializing activities, administration of medication, maintaining the cleanliness of a resident's room, and supervision and assisting in the use of durable medical equipment and prescribed therapies. These additional payment amounts are not subject to the optional cap on overall reimbursement specified in §4308.

In States that do not include the hospice benefit in the State plan, Medicaid payment must still be made under certain circumstances for specified services provided in conjunction with Medicare hospice care for dually eligible individuals who reside in Medicaid reimbursed nursing facilities. When such an individual elects the Medicare hospice benefit and the hospice and the facility have a written agreement under which the hospice is responsible for the professional management of the individual's hospice care and the facility agrees to provide room and board to the individual, pay the hospice an amount equal to the amounts allocated under the State plan for room and board in the facility. Medicaid payment to the facility for nursing facility care is discontinued. These room and board amounts are determined as explained in the first paragraph of this section. If the individual is an individual described in §1902(a)(10(A) of the Act, the State must also provide for payment of any coinsurance amounts imposed under §1813(a)(4).

#### 4310. PRIVATE DUTY NURSING SERVICES

A. <u>Background</u>.--Section 1905(a)(8) of the Act includes private duty nursing services in the definition of medical assistance.

Private duty nursing services are optional. You may elect to cover these services under your program.

42 CFR 440.80 defines private duty nursing services as nursing services for recipients who require more individual and continuous care than is available from a visiting nurse or routinely provided by the nursing staff of the hospital or nursing facility, and which are provided:

- o By a registered nurse or a licensed practical nurse;
- o Under the direction of the recipient's physician; and
- o At the State's option, to a recipient in one or more of the following locations:
  - -- His or her own home;
  - -- A hospital; or
  - -- A nursing facility.
- B. <u>Locations Where Services May be Provided.</u>—Private duty nursing services may be provided in a recipient's home, hospital or nursing facility or, for recipients who are eligible for such services in the home, hospital or nursing facility, services may be provided outside of those settings when normal life activities take the recipient outside of those settings.

Although HCFA has directed, in 42 CFR 440.80, that private duty nursing services may only be provided in a recipient's home, hospital or nursing facility, HCFA's interpretation of these regulations was found to be too narrow under the decision in <u>Detsel v. Sullivan</u>. The Court in <u>Detsel</u> found that these regulations were being interpreted in an outdated and narrow manner so as to preclude a claimant who resided at home from receiving Medicaid payment for private duty nursing services rendered during those few hours each day when normal life activities required the claimant to leave home to attend school. The Secretary, the Court found, did not provide a sufficiently reasonable explanation for the limitation on the locations in which private duty nursing services could be provided. Following the <u>Detsel</u> decision, HCFA adopted the policy that for Medicaid recipients who would otherwise be eligible for private duty nursing services pursuant to 42 CFR 440.80, private duty nursing services rendered during those hours when the recipient's normal life activities take him or her outside the home are covered.

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The <u>Detsel</u> decision does not, however, alter the basic requirement specified in 42 CFR 440.80(c) that a recipient be required and authorized to receive private duty nursing services in the home, hospital or nursing facility. Therefore, if a recipient wants to obtain private duty services to attend school or other activities outside of the home but does not need such services in the home, hospital or nursing facility, there is no basis for authorizing private duty nursing services. Rather, only those individuals who require and are authorized to receive private duty nursing services in the home, hospital or nursing facility setting may utilize their approved hours outside of those settings during those hours when normal life activities take the recipient outside of those settings. Any limitations a State chooses to impose on private duty nursing services, including maximum hour limits, are not affected by the policy change occasioned by the <u>Detsel</u> case decision. Total time and payment allowed for such services is not expected to exceed that which would have been allowed strictly in a home setting.

C. Scope of Services.—The scope of optional private duty nursing services is broader than that of nursing services under the mandatory home health benefit. Nursing services under the mandatory home health benefit must be provided inside the home (except for certain situations where recipients may receive such services in nursing facilities). (See 42 CFR 440.70(c).) Such services are defined in 42 CFR 440.70(b)(1) as part-time or intermittent. Under the private duty nursing benefit, nursing services can be offered on a more continuous basis and can be offered outside of the home. Regulations define private duty nursing services as more individual and continuous care than is available from a visiting nurse or institutional staff. HCFA has not defined or established parameters for the terms part-time or intermittent but rather leaves it to the State to define home health nursing services and the terms part-time or intermittent. By controlling the definition of these terms, it is the State which dictates where home health nursing services end and private duty nursing services begin.

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### 4320. CLINIC SERVICES.

A. <u>Background.</u>--Section 1905(a)(9) of the Social Security Act authorizes under the term "medical assistance," payment for clinic services. As amended by the Deficit Reduction Act of 1984, section 1905(a)(9) describes clinic services as "services furnished by or under the direction of a physician without regard to whether the clinic itself is administered by a physician." The purpose of the 1984 amendment was to clarify that while clinic services have to be provided under the direction of a physician, the clinic does not have to be administered by a physician. This clarification was needed because the physician direction requirement, which has been a requirement for clinic services since the beginning of the Medicaid program, has been in certain cases interpreted erroneously to mean that clinic administrators had to be physicians.

Regulations at 42 CFR 440.90 define clinic services as preventive, diagnostic, therapeutic, rehabilitative, or palliative items or services that--

- 1. are provided to outpatients;
- 2. are provided by a facility that is not part of a hospital but is organized and operated to provide medical care to outpatients; and
- 3. except in the case of nurse-midwife services, as specified in 440.165, are furnished by or under the direction of a physician or dentist.
- Physician Direction Requirement.--Regulations at 42 CFR 440.90 limit coverage of clinic services to situations in which services are furnished under the direction of a physician. As stipulated by section 1905(a)(9) of title XIX of the Social Security Act, this requirement does not mean that the physician must necessarily be an employee of the clinic, or be utilized on a full time basis or be present in the facility during all the hours that services are provided. However, each patient's care must be under the supervision of a physician directly affiliated with the clinic. To meet this requirement, a physician must see the patient at least once, prescribe the type of care provided, and, if the services are not limited by the prescription, periodically review the need for continued care. Although the physician does not have to be on the premises when his/her patient is receiving covered services, the physician must assume professional responsibility for the services provided and assure that the services are medically appropriate. Thus, physicians, who are affiliated with the clinic, must spend as much time in the facility as is necessary to assure that patients are getting services in a safe and efficient manner in accordance with accepted standards of medical and dental practice. For a physician to be affiliated with a clinic, there must be a contractual agreement or some other type of formal arrangement between the physician and the facility by which the physician is obligated to supervise the care provided to the clinic's patients. Some clinics will require more physician involvement than one person can provide. The size of the clinic and the type of services it provides should be used to determine the number of physicians that must be affiliated with a clinic to meet the physician direction requirement. Also, each clinic must have a medical staff which is licensed by State law to provide the medical care delivered to its patients.

- C. Coverage Options.--Clinic services, as defined by 42 CFR 440.90, do not include services provided by hospitals to outpatients. Outpatient hospital services, which are authorized by the regulations at 42 CFR 440.20, are separate and distinct from clinic services. As defined by the regulations, clinic services must be provided by a facility that is not part of a hospital but is organized and operated to provide medical care to outpatients. Thus, clinic services, in accordance with 42 CFR 440.90, must be provided by a freestanding facility, which means that the clinic may not be part of a hospital. However, a clinic may be located in the same building as a hospital, as long as there is no administrative, organizational, financial or other connection between the clinic and the hospital. Clinic services are optional; States may or may not elect to cover these services under their Medicaid programs. There are different types of freestanding clinics that are organized and operated to provide medical care to outpatients, and different types of clinic services that are available. If a State elects to cover clinic services, it may choose the type of clinics or clinic services that are covered, provided that the services constitute medical or remedial care. Thus, a State may provide coverage for some but not all kinds of clinic services.
- D. Provision of Clinic Services to Residents of SNFs, ICFs, AND ICFs/MR.--Clinic services are defined in part, at 42 CFR 440.90, as services that are provided to outpatients. At 42 CFR 440.2, an outpatient is defined as a patient who is receiving professional services at an organized medical facility, or distinct part of such a facility, neither of which is providing the patient with room and board and professional services on a continuous 24-hour-a-day basis.

The definition of outpatient does not exclude residents of title XIX long term care facilities from receiving clinic services either through an arrangement between the facility and the clinic or from a clinic which is chosen by the resident. However, because of the regulatory requirement that clinic services may be provided to outpatients only, the clinic from which they receive services may not provide them with room and board and professional services on a continuous 24-hour-a-day basis. Futhermore, because of the outpatient requirement, eligibility for clinic services is limited to those patients:

- 1. who for the purpose of receiving necessary health care go or are brought to a clinic, or other site at which the clinic staff is available; and
  - 2. who the same day leave the site at which the services are provided.

Thus, this requirement precludes residents of skilled nursing facilities, intermediate care facilities and intermediate care facilities for the mentally retarded from receiving clinic services that are provided in the long term care facility itself. Therefore, these services must be provided at a location which is not a part of the long-term care facility. While such services, if provided at the location of the facility, may not be covered as clinic services, they could be covered as long term care services if included in the package of institutional services provided to the residents of the facility.

# 4370. LESS THAN EFFECTIVE AND IDENTICAL, RELATED OR SIMILAR DRUGS

A. <u>Background</u>.--Less than effective (LTE) drugs are drugs that the Food and Drug Administration (FDA) has proposed to withdraw from the market in a notice of opportunity for a hearing (NOOH) because there is a lack of substantial evidence of effectiveness for all labeled indications and because the Secretary has not determined there is compelling justification for their medical need. Any identical, related or similar (IRS) drugs to those LTE drugs subject to the NOOH are also included in this provision.

Effective October 1, 1981, §2103 of OBRA 1981 terminated Federal financial participation (FFP) under Medicaid for drugs that the FDA has determined to be LTE for which the Secretary has not determined there is a compelling justification for their medical need and for any drug product that is IRS to those drugs subject to the NOOH. However, subsequent legislation led to delays in the implementation of this provision and HCFA continued to pay for these drugs between December 15, 1981 and September 30, 1982. Section 115 of TEFRA provides for implementation of §2103 of OBRA 1981.

States have used the LTE/IRS lists published by HCFA in 1989 as a reference tool in identifying LTE and IRS drugs. HCFA held States accountable for identifying LTE and IRS drugs and did not permit States to claim FFP for expenditures for such drugs.

B. Responsibility for Identifying LTE and IRS Drugs.--Effective January 1, 1993, the responsibility for identifying LTE and IRS drugs for which title XIX FFP is prohibited rests with HCFA. The former policy, which held States responsible for identifying LTE and IRS drugs, has led to disallowances of FFP claimed by the States and, in general, was ineffective both in preventing State payments for LTE and IRS drugs and in minimizing recipient use of LTE and IRS drugs. Audits performed by the Office of the Inspector General found that States were not particularly effective in identifying IRS drugs. State to State variation existed, and HCFA took disallowances against States for Medicaid FFP claimed for payments for these drugs. In appeals of the disallowance decisions, the Departmental Appeals Board upheld the disallowances and noted that it does "... not condone a dangerously passive approach to the problem of ineffective drugs. Medicare and Medicaid beneficiaries' use of ineffective drugs can be hazardous, and the State clearly had an obligation to move as quickly as it reasonably could to stop reliance on these drugs.' This change in policy recognizes the inherent difficulty associated with identifying LTE and IRS drugs. It also recognizes that States continue to have particular difficulty in identifying IRS drugs, and that change is necessary to minimize recipient use and Medicaid expenditures for ineffective drugs.

In an effort to develop a comprehensive file of LTE and IRS drugs, HCFA and the FDA have entered into an ongoing interagency agreement. Both agencies agree to share certain specified information, on an established periodic basis, in order to produce a comprehensive file of both LTE and IRS drugs for which

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FFP is prohibited. The agreement between HCFA and FDA provides for an exchange of information, on an as needed basis, but at least quarterly. HCFA will send to the FDA each quarter a listing which contains every drug product marked as LTE or IRS on the HCFA data base. Each State Medicaid agency will continue to receive a quarterly drug pricing tape file which contains the DESI indicator field values as specified in the data dictionary for that tape file.

If you have questions about drug products included on the list, contact HCFA at the following address:

Health Care Financing Administration Medicaid Bureau Office of Medicaid Management Division of Payment Systems Drug Rebate Operations Branch Room 273 East High Rise Building 6325 Security Blvd. Baltimore, MD 21207

In addition, because the FDA has not yet identified all LTE and IRS drugs which are still on the market, as you become aware of additional drugs or suspect additional drugs should be, but are not included, on the quarterly file, bring these products to HCFA's attention. When necessary, HCFA will consult with the FDA, clarify any discrepancies or issues that you or other interested parties may raise about the file, and amend the file to reflect the clarifications.

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## 4375. TUBERCULOSIS RELATED SERVICES

- A. <u>Background.</u>--Section 13603 of OBRA 1993, P.L. 103-66, amends §1902(a)(10) of the Act to allow States to provide tuberculosis (TB) related services to low income persons infected with TB. Section 13603 also created §1902(z) of the Act, which describes who can qualify as a TB-infected individual and lists the TB-related services these individuals can receive. In addition, §13603 amended the list of Medicaid services in §1905(a) of the Act by adding a new category of TB-related services to §1905(a)(19). Also, §13603 amended §1915(g)(1) of the Act to say that a State can limit case management services to TB-infected individuals and amended the matter following §1902(a)(10)(F) of the Act to provide that individuals who are eligible for Medicaid only because they are TB-infected are limited to receiving the TB-related services listed in §1902(z)(2) of the Act. Effective January 1, 1994, States have the option of providing coverage to individuals infected with TB.
- B. <u>Definition of Services</u>.--Services available to persons who are eligible on the basis of being TB-infected are limited to those listed in §1902(z) of the Act as listed below.
  - o Physicians' services and services described in §1905(a)(2) of the Act;
- o Laboratory and X-ray services, including services to diagnose and confirm the presence of infection;
  - o Clinic services and Federally qualified health center services;
  - o Prescribed drugs;
  - o Case management services as defined in §1915(g)(2) of the Act; and
- o Services, other than room and board, designed to encourage completion of regimens of prescribed drugs by outpatients, including services to observe directly the intake of prescribed drugs.

The listed services are available only if they relate to treatment of TB. However, make the determination based on the individual's circumstances as to whether any particular service relates to the treatment of TB. For example, some prescribed drugs for the treatment of TB can cause side effects which may require additional care by specialists, such as ophthalmologists, and the prescription of additional drugs to treat the side effects. You may cover these services as being TB-related services. However, the treatment of conditions, such as a broken ankle or drug addiction, are not considered to be TB-related.

With the exception of services designed to encourage completion of drug regimens, each of the outpatient services listed above corresponds to a service category already available under Medicaid. Existing Medicaid program requirements apply to the benefits available to TB-infected individuals. Prescribed drugs must meet requirements in 42 CFR 440.120, 441.25, 447.331 and 447.332, and drug rebate provisions as specified in the Act. HCFA believes the services designed to encourage completion of drug regimens vary between States and therefore is taking a broad interpretation of this provision so that you can design the best program appropriate to your needs. Clearly, any services which may be covered under §1905 of the Act, with the exception of inpatient services and room and board, may be available to the extent the services are

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related to completion of a prescribed drug regimen. This may, for example, include transportation to and from necessary treatment services, in-home monitoring of the beneficiary's illness and adherence to a prescribed drug regimen, and patient education and anticipatory guidance which may include services provided to family members that are directly related to ensuring that the beneficiary completes the prescribed drug regimen. In addition, this benefit may also encompass other medical services not otherwise included under §1905(a) of the Act that encourage completion of the drug regimen. For example, you may cover pick-up and delivery of prescribed drugs as long as this service is not generally provided for free in the community, or you may cover other medical services designed to minimize barriers to completion of a prescribed drug regimen. However, nonmedical services are excluded. For example, nonmedical services include monetary incentives or gifts used as an incentive to induce beneficiaries to complete drug regimens.

You must specify in your State plan any services you make available under the benefit designed to encourage outpatients to complete regimens of prescribed drugs.

Under 42 CFR 440.230, you must provide each service in a manner that is sufficient in amount, duration, and scope to reasonably achieve its purpose. Therefore, if all or some of the above services are provided, you must ensure that they effectively treat individuals infected with TB.

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### 4385. PREVENTIVE SERVICES

A. <u>Background and Definition</u>.--Medicaid program funding supports preventive care in a variety of contexts. The preventive aspects of some services (such as outpatient hospital services, clinic services, and dental services) are specifically included in the definition of those services in Medicaid regulations. The mandatory Early and Periodic Screening, Diagnosis and Treatment program for individuals under age 21 (EPSDT) also has a definite preventive orientation.

In addition to including preventive care as an integral component of other covered services, each State has the option of covering preventive care as a separate benefit under its Medicaid program, as authorized by sections 1905(a)(13) and 1902(a)(10) of the Act. Federal regulations (42 CFR 440.130(c)) define preventive services under this benefit as "... services provided by a physician or other licensed practitioner of the healing arts within the scope of his practice under State law to--(1) Prevent disease, disability, and other health conditions or their progression; (2) Prolong life; and (3) Promote physical and mental health and efficiency."

Additional information on preventive services under Medicaid appears in a notice (BERC-285-N) in the <u>Federal Register</u> of March 27, 1984 (49 FR 11717).

- B. Coverage of Services.--In general usage, the term "preventive services" encompasses both personal preventive services performed on a one-to-one basis (such as administering immunizations or screening for disease) and community preventive efforts that do not involve direct patient care (such as water purification). However, for Medicaid coverage of preventive services, a distinction is made between those services that are medical or remedial in nature and those that are not. The statute defines Medicaid as a program of medical assistance, and repeatedly uses the terms "medical" and "remedial" to describe the general types of care for which Medicaid will make payment. (See §§ 1903(a)(1), 1905(a)(6), and 1905(a)(21) of the Act.) Since the inception of the Medicaid program, this medical-remedial orientation has been interpreted to include those services that:
  - o involve direct patient care; and
- o are for the express purpose of diagnosing, treating or preventing (or minimizing the adverse effects of) illness, injury or other impairments to an individual's physical or mental health.

In order for a service to be covered, it must <a href="mailto:meet\_both">meet\_both</a> of these elements. Therefore, preventive services that involve no direct patient care, such as services applied at the community level, or environmental services dealing exclusively with an individual's surroundings rather than the individual, are not covered. Further, even if a particular preventive service does involve some direct contact with the individual, it cannot be covered unless it also is expressly for the purpose of addressing the individual's physical or mental health. For example, a social service may be furnished directly to an individual client, but it typically is directed broadly at the individual's overall well-being rather than specifically at the individual's health. While a social service, in the course of addressing an individual's basic life needs (adequate food, housing, income, etc.), may indirectly affect the individual's health as well, it would not be covered under Medicaid because it is

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not in itself <u>directly</u> and <u>primarily</u> concerned with the individual's health. Some examples of coverable preventive services, noncovered preventive services at the community level, and nonmedical services that address broader social or environmental concerns are as follows:

- o The topical application of fluorides or dental sealants furnished directly to a Medicaid recipient can be covered under Medicaid. However, activities such as fluoridation of a community's water supply are not covered, since there is no direct patient care involved.
- o Preventive group counseling by a licensed practitioner of the healing arts (acting within the scope of practice under State law) can be covered when it allows direct, one-to-one interaction between the counselor and the individual recipient. By contrast, disseminating general information on prevention through the mass media involves no direct patient care, and is not covered.
- o Investigations to determine the source of a child's elevated blood lead level are patient-oriented and, therefore, covered; however, environmental interventions to remove the lead source are not.
- o Nonmedical preventive services that address broader social or environmental concerns are not covered under Medicaid, even when furnished directly to individuals (e.g., counseling on the importance of smoke detectors, or of keeping door and window screens in good repair; instruction on traffic safety).
- C. <u>State Preventive Initiatives.</u>—A number of States already offer an effective package of preventive care under their Medicaid programs. Other States have included Medicaid coverage of at least some preventive services. Often, however, a wide range of preventive services may already be available in a State, but the services are fragmented among numerous agencies and programs in addition to Medicaid. As a result, Medicaid recipients may not receive a complete and coordinated program of preventive care.

If you are interested in initiating or expanding a Medicaid preventive care effort, you can take a two-fold approach:

- o Medicaid funding of the medically-oriented personal preventive services for which Federal financial participation (FFP) is available under title XIX; and
- o increased coordination between Medicaid and other programs that fund or provide preventive care, including referral to social and environmental programs and services.

At present, there is no uniformly accepted nationwide standard that specifies a single set of preventive services, or a particular schedule for their delivery, as being the most effective (and we do not attempt to prescribe one here). We encourage you, in developing an approach to preventive care, to consult with local health authorities and organizations to help identify the most effective set of preventive services for your Medicaid population.

1. <u>Evaluating State Plan Amendments.</u>—While we believe you should have flexibility in designing your own package of preventive care, there are certain general criteria that HCFA applies when reviewing proposed plan amendments for preventive services coverage. The proposed services must:

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- o Be preventive in nature and fit within the basic medical-remedial framework of the Medicaid program (see subsection B);
  - o Be directed at the patient rather than at the patient's environment;
- o Not be otherwise available to recipients without cost, nor may they duplicate other Federally-funded services; and
- o Not entail an additional payment for a service which is logically an inherent part of otherwise paid-for services. For example, in the course of furnishing covered treatment to a recipient, a physician sometimes will provide counseling of a preventive nature. This counseling is an inherent part of the covered services for which payment is already being made under the physician services benefit; thus, a separate, additional payment under the preventive benefit for the counseling aspect of the services would not be made, since this would represent a duplicate payment.

Although the Medicaid statute does not preclude you from funding experimental types of care, HCFA encourages you to consider, in addition, the following guidelines when developing proposals for coverage of preventive services, in order to achieve maximum effectiveness:

- o When considering coverage of services to detect disease in its early state, focus on those services that have been proven to be safe and reliable, and that detect diseases for which an effective intervention exists.
- o Make sure the services proposed to prevent occurrence of disease or disability (including those to modify predisposing risk factors) have a demonstrated efficacy in preventing disease or disability.
- 2. Coordination with Other Programs.—The benefits an individual derives from Medicaid-covered preventive services can be significantly enhanced when these services are coordinated with the preventive care available under other programs. In an effort to maximize scarce Medicaid dollars available for preventive services and avoid costly duplication of services, many States have sought the cooperation and active participation of other public as well as voluntary health agencies, such as State, county, and local health agencies, Head Start, community health centers, migrant health centers, and others. HCFA encourages you to follow this example if you are considering the inclusion of preventive services in your plan. Coordination can be achieved through interagency agreements, informal cooperative arrangements and increased referrals between the Medicaid agency and other programs that offer preventive care.

Medicaid regulations (42 CFR Part 431, Subpart M) contain requirements and options for interagency agreements. These include the following:

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- o The Medicaid agency is required to have an interagency agreement with the State health agency and the State vocational rehabilitation agency, as well as the title V program. The agreements are designed to make maximum use of the services of these agencies.
- o The Medicaid agency, in addition, may execute interagency agreements with other health and social service agencies and organizations, involving services that utilize Federal as well as State or local funds. For children, youth and pregnant women, these programs could include Head Start, title XX (Social Services Block Grant), certain education programs, and the Special Supplemental Food Program for Women, Infants, and Children (WIC). Effective coordination between the medically-oriented preventive services offered under a State's Medicaid program and the nutrition services offered by the WIC Program, for example, can play an important role in a State's overall strategy to lower its infant mortality rate.

Often, a recipient may not know about the full range of preventive services that are available under various programs, or how to obtain those services. The Medicaid agency can perform a valuable referral function for Medicaid recipients, and can help to supplement the preventive services available to them under the State plan, by directing them to appropriate preventive care available from other sources. In certain situations, you can also help to utilize available Federal funds most effectively by directly coordinating Medicaid-funded preventive services activities with those of other programs offering related services. Some types of services for which such coordination is appropriate would include examinations, immunizations and treatment services, and such activities as informing recipients about available health services, assisting recipients with transportation to health services and health care case management (ensuring continuity of care).

The increased use of preventive services offers the potential for improving individual health and reducing the cost of treating illness and injury. If you have not already done so, consider reviewing your existing program for ways to make a wider range of preventive services available and accessible to your Medicaid population.

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### 4390. INSTITUTIONS FOR MENTAL DISEASES

- A. <u>Statutory and Regulatory Provisions</u>.--The statutory provisions relating to institutions for mental diseases (IMDs) include two categories of covered services and a broad payment exclusion that can preclude payment for services provided to certain individuals in both participating and non-participating facilities.
- 1. <u>IMD Coverage</u>.--The original Medicaid legislation (P.L. 89-97) included a benefit for individuals 65 years of age or older who are in hospitals or nursing facilities that are IMDs. This provision is in §1905(a)(14) of the Act and regulations relating to this benefit are in Subpart C of 42 CFR 441.
- In 1972, the Medicaid program was expanded (P.L. 92-603) to include inpatient psychiatric hospital services for individuals under age 21, or, in certain circumstances, under age 22. This provision is in §1905(a)(16) of the Act. Authority for using additional settings was enacted in P.L. 101-508. This benefit is currently being provided in a wide variety of psychiatric facilities. Regulations for this benefit are in Subpart D of 42 CFR 441.

Both IMD benefits are optional, except that inpatient psychiatric services for individuals under age 21 must be provided in any State as early and periodic screening, diagnosis and treatment (EPSDT) services if they are determined to be medically necessary.

- 2. <u>IMD Exclusion</u>.--The IMD exclusion is in §1905(a) of the Act in paragraph (B) following the list of Medicaid services. This paragraph states that FFP is not available for any medical assistance under title XIX for services provided to any individual who is under age 65 and who is a patient in an IMD unless the payment is for inpatient psychiatric services for individuals under age 21. This exclusion was designed to assure that States, rather than the Federal government, continue to have principal responsibility for funding inpatient psychiatric services. Under this broad exclusion, no Medicaid payment can be made for services provided either in or outside the facility for IMD patients in this age group.
- 3. <u>IMD Definition.</u>--In 1988, P.L. 100-360 defined an institution for mental diseases as a hospital, nursing facility, or other institution of more than 16 beds that is primarily engaged in providing diagnosis, treatment, or care of persons with mental diseases, including medical attention, nursing care, and related services. This definition is in §1905(i) of the Act and in 42 CFR 435.1009. The regulations also indicate that an institution is an IMD if its overall character is that of a facility established and maintained primarily for the care and treatment of individuals with mental diseases.

Facilities with fewer than 17 beds that specialize in treating persons with mental disorders can provide the types of services discussed in item 1 if they meet the regulatory requirements to provide these institutional benefits, but these facilities are not technically IMDs. Because IMDs are defined to be institutions with more than 16 beds, the IMD exclusion applies only to institutions with at least 17 beds.

B. Guidelines for Determining What Constitutes an Institution.--When it is necessary to determine whether an institution is an IMD, the IMD criteria listed in subsection C must be applied to the appropriate entity. In most cases, there is no difficulty in determining what entity to apply the criteria to. But in cases in which multiple components are involved, it may be necessary for the HCFA regional office (RO) to apply the following guidelines

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to identify the institution to be assessed. Components that are certified as different types of providers, such as NFs and hospitals, are considered independent from each other.

- 1. Are all components controlled by one owner or one governing body?
- 2. Is one chief medical officer responsible for the medical staff activities in all components?
- 3. Does one chief executive officer control all administrative activities in all components?
  - 4. Are any of the components separately licensed?
- 5. Are the components so organizationally and geographically separate that it is not feasible to operate as a single entity?
- 6. If two or more of the components are participating under the same provider category (such as NFs), can each component meet the conditions of participation independently?

The RO may also use other guidelines that it finds relevant in a specific situation. If the answer to items 1, 2, or 3 is "no," or the answer to items 4, 5, or 6 is "yes," for example, there may be a separate facility/component. If it is determined that a component is independent, the IMD criteria in subsection C are applied to that component unless the component has 16 or fewer beds.

- C. Guidelines for Determining Whether Institution Is an IMD.--HCFA uses the following guidelines to evaluate whether the overall character of a facility is that of an IMD. If any of these criteria are met, a thorough IMD assessment must be made. Other relevant factors may also be considered. For example, if a NF is being reviewed, reviewers may wish to consider whether the average age of the patients in the NF is significantly lower than that of a typical NF. A final determination of a facility's IMD status depends on whether an evaluation of the information pertaining to the facility establishes that its overall character is that of a facility established and/or maintained primarily for the care and treatment of individuals with mental diseases.
  - 1. The facility is licensed as a psychiatric facility;
  - 2. The facility is accredited as a psychiatric facility;
- 3. The facility is under the jurisdiction of the State's mental health authority. (This criterion does not apply to facilities under mental health authority that are not providing services to mentally ill persons.);
- 4. The facility specializes in providing psychiatric/psychological care and treatment. This may be ascertained through review of patients' records. It may also be indicated by the fact that an unusually large proportion of the staff has specialized psychiatric/psychological training or that a large proportion of the patients are receiving psychopharmacological drugs; and
- 5. The current need for institutionalization for more than 50 percent of all the patients in the facility results from mental diseases.

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D. <u>Assessing Patient Population</u>.--The review team applying the guidelines must include at least one physician or other skilled medical professional who is familiar with the care of mentally ill individuals. No team member may be employed by or have a significant financial interest in the facility under review.

In applying the 50 percent guideline (see §4390.C.2), determine whether each patient's current need for institutionalization results from a mental disease. It is not necessary to determine whether any mental health care is being provided in applying this guideline.

For purposes of determining whether a facility is subject to the IMD exclusion, the term "mental disease" includes diseases listed as mental disorders in the International Classification of Diseases, 9th Edition, modified for clinical applications (ICD-9-CM), with the exception of mental retardation, senility, and organic brain syndrome. The Diagnostic and Statistical Manual of Mental Disorders (DSM) is a subspecification of the mental disorder chapter of the ICD and may also be used to determine whether a disorder is a mental disease.

If it is not possible to make the determination solely on the basis of an individual's current diagnosis, classify the patient according to the diagnosis at the time of admission if the patient was admitted within the past year. Do not include a patient in the mentally ill category when no clear cut distinction is possible.

To classify private patients when review of their records is not possible, rely on other factors such as the surveyor's professional observation, discussion with staff of the overall character and nature of the patient's problems, and the specialty of the attending physician.

When the 50 percent guideline is being applied in a NF, the guideline is met if more than 50 percent of the NF residents require specialized services for treatment of serious mental illnesses, as defined in 42 CFR 483.102(b). Facilities providing non-intensive care for chronically ill individuals may also be IMDs. All NFs must provide mental health services which are of a lesser intensity than specialized services to all residents who need such services. Therefore, in applying the 50 percent guidelines, it is important to focus on the basis of the patient's current need for NF care, rather than the nature of the services being provided.

E. <u>Chemical Dependency Treatment Facilities.</u>—The ICD-9-CM system classifies alcoholism and other chemical dependency syndromes as mental disorders.

There is a continuum of care for chemical dependency. At one end of the spectrum of care, treatment follows a psychiatric model and is performed by medically trained and licensed personnel. If services are psychological in nature, the services are considered medical treatment of a mental disease. Chemically dependent patients admitted for such treatment are counted as mentally ill under the 50 percent guideline. Facilities with more than 16 beds that are providing this type of treatment to the majority of their patients are IMDs.

At the other end of the spectrum of care are facilities that are limited to services based on the Alcoholics Anonymous model, i.e., they rely on peer counseling and meetings to promote group support and encouragement, and they primarily use lay persons as counselors. Lay counseling does not constitute medical or remedial treatment. (See 42 CFR 440.2(b).) Do not count patients

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admitted to a facility only for lay counseling or services based on the Alcoholics Anonymous model as mentally ill under the 50 percent guideline. If psychosocial support provided by peers or staff without specialized training is the primary care being provided in the facility, the facility is not an IMD. The major factor differentiating these facilities from other chemical dependency treatment facilities is the primary reliance on lay staff.

Federal matching funds may not be claimed for institutional services when lay/social treatment is the primary reason for the inpatient stay. Facilities may not claim Medicaid payment for providing covered medical or remedial services in a nursing facility or hospital to patients admitted for treatment of chemical dependency and simultaneously claim that they are providing only lay or social services to those same patients when the 50 percent guideline is being applied. Facilities also may not avoid having their chemically dependent patients counted as mentally ill under the 50 percent guideline by withholding appropriate treatment from those patients. Facilities failing to provide appropriate treatment to patients risk termination from the program.

In determining whether a facility has fewer than 17 beds, it is not necessary to include beds used solely to accommodate the children of the individuals who are being treated. Children in beds that are not certified or used as treatment beds are not considered to be patients in the IMD and therefore are not subject to the IMD exclusion if they receive covered services while outside the facility.

4390.1 Periods of Absence From IMDs.--42 CFR 435.1008(c) states that an individual on conditional release or convalescent leave from an IMD is not considered to be a patient in that institution. These periods of absence relate to the course of treatment of the individual's mental disorder. If a patient is sent home for a trial visit, this is convalescent leave. If a patient is released from the institution on the condition that the patient receive outpatient treatment or on other comparable conditions, the patient is on conditional release.

If an emergency or other need to obtain medical treatment arises during the course of convalescent leave or conditional release, these services may be covered under Medicaid because the individual is not considered to be an IMD patient during these periods. If a patient is temporarily transferred from an IMD for the purpose of obtaining medical treatment, however, this is not considered a conditional release, and the patient is still considered an IMD patient.

The regulations contain a separate provision for individuals under age 22 who have been receiving the inpatient psychiatric services benefit defined in 42 CFR 440.160. This category of patient is considered to remain a patient in the institution until he/she is unconditionally released or, if earlier, the date he/she reaches age 22.

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